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10/027,877

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William Earl Webler

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06/09/2009

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/027,877 | Applicant(s) WEBLER, WILLIAM EARL | |
| | Examiner JONATHAN ML FOREMAN | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-18,26 and 31 is/are rejected.
- 7) ☒ Claim(s) 19,20,27-30 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/09 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 5 – 9, 11, 14 – 18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al.

In regard to claims 1, 3, 5 – 9, 11, 14 – 18 and 26, Tay et al. disclose an elongate member as a needle, in that Tay et al. discloses the probe as a hollow elongated member (Col. 20, lines 12 – 18), or rod insertable into a body. The needle includes a distal opening, and a lumen (148; Figure 21) extending from a proximal end to the distal opening (Col. 16, lines 12 – 15) in communication with the distal opening capable of allowing a substance to be delivered through the lumen. The distal end of the needle is capable of puncturing skin (Col. 15, line 65 – Col. 16, line 1). Tay et al. disclose using a thermally conductive heating element comprising a wire whose electrical resistance changes

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in response to a change in temperature (Col. 20, lines 45 – 49) in order to determine the depth of a vessel wall. It would have been obvious to one having ordinary skill in the art to position this heating element on the distal portion of the needle disclosed by Tay et al. in that the distal portion of the needle is the portion inserted into the vessel. Tay et al. disclose anemometry circuitry and comparing a first resistance and a second resistance of the at least one heating element to indicate a change of conditions related to a distance of penetration of the heating element (Col. 20, lines 48 – 54). Tay et al. disclose a first condition and a second condition related to a distance of penetration of the thermally conductive heating element into a tissue from a fluid boundary with the tissue (Col. 20, lines 50 – 54). Tay et al. disclose an embodiment having an opening (184) positioned proximal of the distal tip (Figure 26). The heating element is less than the thickness of the tissue in which it is inserted. In order to operate the device as disclosed by Tay et al. must include a first and second lead coupled to the at least one heating element in order to create a completed circuit. However, Tay et al. fails to disclose the anemometry circuitry comprising the heating element and a variable resistor as resistive circuit element. Lull et al. teaches a circuit for use in an anemometer (Col. 17, lines 10 - 15) comprising a balanced circuit (Col. 11, lines 40 – 46) having the heating element (R_1 , R_2) and a variable resistor (Col. 7, lines 49 - 52) as resistive circuit element and an amplifier coupled to the circuit (Col. 7, line 25 – Col. 8, line 22). It would have been obvious to one having ordinary skill in the art to modify the circuitry as disclosed by Tay et al. to include an interface to the balanced circuit as disclosed by Lull et al. in order to compare variations in the resistance of the heating elements (Col. 17, lines 10 – 15). Tay et al. in view of Lull et al. fail to disclose the heating element being between 0.010 inches and 0.400 inches. However, a change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA

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1955). In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

4. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 2 and 11 above, and further in view of U.S. Patent No. 3,470,604 to Zenick.

In reference to claims 4 and 13, Tay et al. in view of Lull et al. disclose a needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the needle as disclosed by Tay et al. in view of Lull et al. out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.

5. Claims 10 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 5,873,835 to Hastings et al.

In regard to claims 10 and 18, Tay et al. in view of Lull et al. fail to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teach a portion of the elongate member being electrically conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically coupled to a second end of the heating element (Col. 11, lines 33 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the

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elongate member as disclosed by Tay et al. in view of Lull et al. to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 – 35).

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied above, and further in view of U.S. Patent No. 6,110,183 to Cope.

In regard to claim 12, Tay et al. in view of Lull et al. disclose the needle having an outer diameter between 0.009 inches and 0.134 inches (Col. 19, line 56 – Col. 20, line 18), but fail to disclose the distal end being sharpened. Cope discloses an apparatus for insertion into a puncture of a patient (Col. 4, lines 55 – 58). Cope teach the use of a sharpened distal end (33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end disclosed by Tay et al. in view of Lull et al. to be sharpened as taught by Cope in order to facilitate entry into the patient (Col. 4, lines 61 - 63).

Allowable Subject Matter

7. Claims 19, 20, 27 - 30 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 4/2/09 have been fully considered but they are not persuasive. In regards to the claims being rejected under 35 U.S.C. § 103 (a) as being obvious over US Patent No. 6,063,085 to Tay et al. in view of US Patent No. 6,539,792 to Lull et al., Applicant asserts that

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a prima facie case of obviousness has not been established. However the Examiner disagrees. The Examiner asserts that Tay et al. in view of Lull et al., when combined, teach or suggest all of the claim limitations (See above). The Examiner asserts that there is a reasonable expectation of success in that merely one anemometry circuit has been replaced by another. Each anemometry circuit as disclosed by Tay et al. and Lull et al. is used to compare a first resistance and a second resistance of at least one heating element. The Examiner asserts that the suggestion or motivation to combine Tay et al. and Lull et al. is found in the references themselves or in the knowledge generally available to one having ordinary skill in the art. At Col. 20, lines 43 – 54, Tay et al. teaches that other techniques may be used to determine the depth of a vessel wall. Tay et al. suggests using a flow anemometer, which comprises two thin coils of wire spaced slightly apart on a probe and heated by passing electrical current there through, causing resistance heating. By constructing the coils out of wire with a temperature-dependent resistance, the position of the probe with respect to the vessel can be determined by comparing the resistance between the two coils, because blood flow past a coil within the artery will reduce its temperature, and hence its resistance, compared to a coil outside of the artery. However, Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer. It is noted that a rigid object having a diameter as disclosed by Tay et al. is capable of puncturing skin depending on the amount of force applied. It would have been obvious to one having ordinary skill in the art to position the heating element on the distal portion of the needle disclosed by Tay et al. in that the distal portion of the needle is the portion inserted into the vessel. Positioning the heating element at a portion proximal the distal portion would not be beneficial in that the probe would be required to pierce deeper into a patient before the depth of a vessel wall could be determined. Tay et al. disclose

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indicating a change of conditions related to a distance of penetration into a tissue from a fluid boundary with the tissue (Col. 20, lines 50 – 54).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736